

REMARKS

Claims 57-62, 64-73, 75, and 77-79 as amended remain in this application and are submitted for the Examiner's review and consideration. In this Response, Applicants have amended certain claims. In light of the Final Office Action, Applicants believe these amendments serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicants respectfully submit that the claim amendments do not limit the range of any permissible equivalents.

Claims 66 and 70 were rejected under 35 U.S.C. § 102(e) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 5,234,425 to Fogarty *et al.* ("Fogarty"). Claims 66 and 71 were rejected under 35 U.S.C. § 102(b) as anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. Patent No. 4,706,670 to Andersen *et al.* ("Andersen"). For the reasons set forth below, Applicants respectfully submit that these claims are not taught or suggested by Fogarty or Andersen.

Fogarty is directed to a variable diameter sheath method and apparatus for use in body passages. A sheath 10 is elongate and proportioned to expand, when relaxed, to an outside diameter approximately equal to the inside diameter of the body passage within which the sheath is to be used. Fogarty, 3:27-32. In a typical embodiment, the sheath has an expanded relaxed diameter of from 6 to 7 mm and a contracted reduced diameter of 2 to 3 mm. *Id.*, 3:33-35. In short and as stated in Fogarty, "when in a passive state, the sheath assumes the expanded-diameter condition." *Id.*, 2:22-25.

Despite this clear teaching that the Fogarty stent naturally assumes an expanded condition (*i.e.* is biased in an expanded condition), the Examiner asserts that if some hypothetical expanding force were applied to sheath 40 and this expanding force were then removed, "the sheath would be biased in the contracted position." The only example of such a hypothetical expanding force provided by the Examiner is a "dilator inserted within" the sheath. As an alternative argument, the Examiner asserts that "the sheath 40 and filaments 42 are obviously resiliently expandable since

sheath 40 is made of resilient material.” Applicants disagree with the Examiner’s positions.

With respect to the latter position, the fact that Fogarty’s sheath is made of a resilient material does not anticipate or make obvious the expandable cannula as claimed in claim 66. For example, claim 66 recites that the sheath is biased in the contracted condition. As disclosed in the specification, a cannula 10 according to one embodiment of the present invention includes an expanding portion 12 with a plurality of wires 16 that are surrounded by an overlying elastic sheath 18. Specification, p. 7, lns. 15-20. The sheath 18 is of a diameter such that it is stressed even when the cannula is fully contracted. *Id.*, p. 8, ln. 27 to p. 9, ln. 1. “Thus the sheath 18 constantly biases the wires 16 radially inwardly toward the axis 22 of the cannula 10.” *Id.*, p. 9, lns. 2-3.

This is the exact opposite of Fogarty, in which there is a bias of the sheath and filaments to the expanded condition. It is unclear how one of ordinary skill of the art would be motivated to modify Fogarty as proposed by the Examiner to do the exact opposite of the teaching of Fogarty.

The Examiner appears to attempt to justify this inconsistency, by asserting that the expanded bias of the Fogarty sheath is “the described intended use.” This is simply not true as the structure of the sheath and filaments makes the expanded bias a structural feature of Fogarty. Additionally, the sheath and the filaments of Fogarty would prevent one of ordinary skill in the art from a use as proposed by the Examiner. Specifically, the filaments would limit, if not eliminate any expansion. *See* Fogarty, 4:37-38. The stylet 36, which runs through the sheath, would also prevent the insertion of a dilator through the sheath as suggested by the Examiner.

As previously noted, the Examiner also rejected independent claims 66 as anticipated by, or in the alternative, as obvious over Andersen. Andersen relates to dilatation catheters which have a shaft having a portion which can be inflated like a balloon. Thus, Andersen is limited to a balloon catheter for enlarging the diameter of a blood vessel and does not anticipate an expandable cannula, as claimed in claim 66. Andersen also does not make obvious such an expandable cannula since the only object that is inserted in the Andersen catheter is a guide wire and it is simply not possible to modify Andersen to obtain the claimed expandable cannula. In fact, Andersen itself makes a distinction between a cannula and a dilatation catheter. *See*

Andersen, 1:27-29. Furthermore, one of the features of Andersen is the three distinct regions of inelastic fibers that allow for inflation of the balloon without any change in the catheter diameter. *Id.*, 4:42-52.

In contrast, one embodiment of the present invention relates to a cannula 10 that is expanded radially outwardly to thereby make a larger central passage 20 for instruments along its entire length. Specification, p. 11, lns. 15-21. The cannula 10 expands radially outwardly along substantially its entire length against the bias of the sheath 18. *Id.*, p. 13, lns. 15-17. Thus, the cannula 10 can accommodate through its central instrument passage 20 a surgical instrument or the like having a diameter along its entire length which is greater than the diameter of the cannula in the contracted condition. *Id.*, p. 13, lns. 17-21. This is not possible with cannulas which expand only along a portion of their length. *Id.*, p. 13, lns. 21-22. It is also not possible with Andersen since the only structure on Andersen that expands is the interior of the balloon and this is a sealed system incapable of receiving any object.

In order to clarify the invention claimed in claim 66, claim 66 has been amended to recite that the expandable cannula includes a sheath having a passage which extends between opposite end portions of said sheath with said array of filaments extending along an inner side of said passage. Claim 66 now further recites that the passage, like the sheath and array of filaments resiliently expands from a contracted condition in which the passage has a relatively small cross sectional size in a plane perpendicular to a longitudinal central axis of the sheath to an expanded condition in which the passage has a relatively large cross sectional size.

Because claim 66 has been amended to include recitations from allowable claim 69, claim 69 has been amended accordingly. Claims 68, 70, and 71 have also been amended to reflect the amendment to claim 66. Entry of this amendment is respectfully requested as the amendments and remarks place the application in condition for allowance, or, at least present the application in better form for appeal.

In light of the foregoing, independent claim 66 is respectfully submitted to be patentable over Fogarty and Andersen. As claims 70 and 71 depend from claim 66 and necessarily include all

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Examiner: M. Thaler

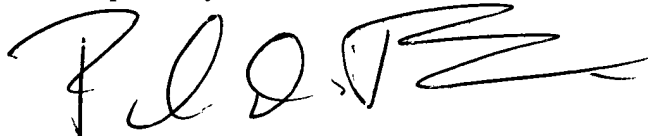
the elements of their base claim, Applicants respectfully submit that these claims are also allowable over the cited references at least for the same reasons.

Finally, Applicants acknowledge with appreciation the continued allowance of claims 57-62, 64, 65, 72, 73, 75, and 77-79.

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due with this submission. However, please charge the required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket no. 780-A02-003-2).

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'P. D. Bianco', with a stylized flourish at the end.

Paul D. Bianco, Reg. # 43,500

Enclosures

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